

UNITED STATES PATENT APPLICATION

Venous Valve Apparatus and Method

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This application claims priority from U.S. Provisional Application Serial No. 60/420,905, filed October 24, 2002, the entire content of which is incorporated herein
5 by reference.

Technical Field

The present invention relates generally to apparatus, systems, and methods for use in a body lumen; and more particularly to a valve apparatus for use in the
10 vasculature.

Background

In human pathology, the proper functioning of venous valves is important. Chronic venous diseases such as chronic venous insufficiency and varicose veins may
15 result in incompetence of venous valves. Venous insufficiency is believed to contribute to various maladies, including chronic venous insufficiency, edema, varicose veins, aching leg pain while standing, lipodermatosclerosis, and ulcerations. Venous insufficiency is essentially caused by venous hypertension and chronic venous stasis due to valvular incompetence both of an idiopathic nature and of a secondary nature
20 following past illnesses of the venous systems.

A replacement venous valve may regulate the direction of the pulsating blood flow so as to limit the occurrence of blood stasis in the region about the valve. By maintaining the direction of blood flow therethrough a new venous valve may alleviate the maladies resulting from valve disorders or venous insufficiency. A replacement
25 valve should therefore permit blood flow in the proper predetermined direction to limit or prevent backflow of the blood in a reverse direction.

BRIEF DESCRIPTION OF DRAWINGS

A detailed description of the invention is hereafter described with specific
30 reference being made to the drawings.

Figure 1 is a perspective view of an embodiment of the invention wherein a portion of a vein is configured to act as a valve.

Figure 2 is a cross-sectional view of the embodiment shown in Figure 1 wherein the configured vein is shown during prograde blood flow.

Figure 3 is a cross-sectional view of the embodiment shown in Figure 1 wherein the configured vein is shown during retrograde blood flow.

Figure 4 is a perspective view of an embodiment of the invention including a saddle for establishing and supporting a region of a vein configured to act as a valve.

5 Figure 5 is a perspective view of an embodiment of the invention including a saddle for establishing and supporting a region of a vein configured to act as a valve.

Figure 6 is a perspective view of the portion of a vein configuration shown in Figure 1 with the ring support of Figure 4 positioned therein.

10 Figure 7 is a side view of a vein having an embodiment of the invention including a catheter assembly for use in configuring a region of the vein to act as a valve positioned therein.

Figure 8 is a side view of the vein containing the embodiment of the invention depicted in Figure 7 shown during balloon deployment.

15 Figure 9 is a side view of the vein containing the embodiment of the invention depicted in Figure 8 shown during evacuation of a region of the vein between the deployed balloons to collapse the region.

Figure 10 is a side view of the vein containing the embodiment of the invention depicted in Figure 9 shown during balloon collapse.

20 Figure 11 is a side view of the vein containing the embodiment of the invention depicted in Figure 10 wherein the saddle is engaged to a portion of the collapsed region of the vein.

25 Figure 12 is a side view of the vein containing the embodiment of the invention wherein the saddle and a portion of the collapsed region of the vein engaged thereto are moved into an adjacent portion of the vein to provide the vein with a valve configuration.

Figure 13 is side view of the vein shown in Figures 7-13 wherein the catheter has been removed from the valve configured region of the vein.

Figure 14 is a perspective view of an embodiment of the invention wherein the valve region comprises a single valve wall or leaflet.

30 Figure 15 is a perspective view of the embodiment shown in Figure 14, with the valve wall or leaflet in the closed configuration.

Figure 16 is a perspective view of an embodiment of the invention wherein the valve region comprises a single valve wall or leaflet.

DETAILED DESCRIPTION

Embodiments of the present invention may include different forms. The description herein provides an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated. For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

The present invention is directed to several embodiments. For example, in at least one embodiment the invention is directed to an apparatus for forming a valve in a vein utilizing the vein itself to form the valve. In some embodiments the apparatus includes a support and/or a fixation device that may be used to form the valve intravenously, extravenously or in a combination of intravenous, and extravenous locations.

In some embodiments the apparatus includes, but is not limited to, one or more ring-like support members or saddles, which retain portions of the vein wall in a position to form a functional valve. In some embodiments the apparatus further includes, but is not limited to, a stent or other implantable and expandable medical device to provide a fold region within the vein through which portions of the vein and support member are positioned to form the valve.

In at least one embodiment the invention is directed to a method of forming a valve utilizing the vein itself. In some embodiments the invention is directed to a method for dissecting the vein from surrounding tissue, thereby freeing the vein to allow longitudinal and axial movement and repositioning of a portion of the vein to form the valve. In some embodiments portions of the reconfigured vein may be tacked together to maintain the valve structure. In some embodiments an expandable member such as a stent is deployed within the vein to provide a point about which an adjacent portion of the vein is folded to provide the valve configuration. In some embodiments one or more saddle members are placed in the reconfigured region of the vein to support the vein and maintain the valve configuration.

In at least one embodiment the invention is directed to a method for forming a valve using entirely percutaneous access methods, or by minimally invasive access methods, or a combination thereof. In some embodiments the invention is directed to a catheter assembly and its methods of use for preparing and/or forming a valve region of a vein by collapsing a region of the vein and/or folding the walls of the vein to provide the vein with a valve configuration. In some embodiments the catheter assembly is

provided with one or more balloons to define a valve region and/or deploy a stent and/or a saddle in order to establish and/or maintain the valve configuration of the vein.

Turning to Figure 1 a first embodiment of the invention is depicted which includes a portion of a vein, indicated generally at reference numeral 10, which is folded over itself to provide the vein with a valve region 12. The valve region 12 acts as a unidirectional blood flow valve in the manner of an existing venous valve. Valve region 12 is provided to the vein 10 by folding a first or outer portion 14 of the vein over a second or inner portion 16 of the vein and retaining the folded configuration by engaging one or more portions of the first portion 14 to adjacent portions of the second portion 16. In at least one embodiment the folding is accomplished endoluminally using a catheter rather than using an external surgical approach.

There are several techniques and devices that may be utilized to form the valve region 12 within the vein as well as to maintain the folded configuration of the valve thereafter. For example, in the embodiment shown in Figure 1, the vein may be endoluminally or surgically manipulated and folded in the manner shown and described herein. To retain the folded configuration of the valve region 12, the outer portion 14 of the folded vein is engaged to the inner portion 16 of the vein at a plurality of points, such as are indicated by reference numerals 18 and 20 in Figures 2 and 3.

In some embodiments valve region 12 may be formed using a vein segment or other autologous or non-autologous biological material and implanted into the desired location to provide valve region 12 in vein 10.

Engagement of selected points of the inner portion 16 and outer portion 14 of the vein has the effect of defining a valve opening 22 with the opposing walls 24 and 26 of the inner portion 16. Depending on the tautness of the region of the vein used to define the opening 22, the opening may also be characterized as a slit. When blood is flowing through the opening or slit 22 in a normal prograde direction, such as when the blood is under positive pressure, as indicated by arrow 28 in Figure 1, the walls 24 and 26 of the inner portion 16 are pushed outward, as indicated by arrows 30 in Figure 2, to allow free flow of blood through the opening 22. However, if for whatever reason, the flow of blood through the vein is reversed or becomes retrograde, i.e., under negative pressure, the pressure exerted on the opening 22 will cause the walls 24 and 26 to collapse inward, as indicated by arrows 32 in Figure 3, thus closing the opening 22 and preventing the retrograde flow.

Vein portions 14 and 16 may be engaged together to maintain the valve region

12 in a variety of different and/or complimentary manners. For example, in the embodiment shown in Figures 2 and 3 the portions may be sutured, tacked, thermally bonded, glued, and/or otherwise secured together at junctions 18 and 20 or at other areas as may be desired to maintain the valve region 12 and provide the unidirectional opening 22.

In some embodiments a biasing member or support device may be inserted within the vein to maintain the folded configuration of the valve region 12 by pushing selected portions of the inner portion 16 against the outer portion 14 to form opening 22.

Some examples of such a support device are shown in Figures 4 and 5, wherein a valve maintaining support includes, but is not limited to, a substantially ring-like member or saddle 40, which may inserted into the vein to maintain the folded configuration of the valve region 12 by biasing portions of the inner portion 16 of the vein 10 against corresponding portions of the outer portion 14 of the vein 10 such as in the manner shown in Figure 6.

As shown in Figures 4 and 5, the saddle 40 may be constructed of one or more wires or bands 42 of material. The saddle may be constructed from one or more metals and/or polymer materials, including shape memory metals such as nitinol, and/or shape memory polymers, and/or bioabsorbable materials. In one embodiment, the material of the saddle can be biocompatible or is coated with one or more biocompatible coatings.

The saddle 40 defines at least two biasing regions 44 and 46 that as a result of inherent biasing tension and/or as a result of transitioning from a reduced state to an expanded shape memory state, push the inner portion 16 of the vein 10 against the outer portion 14 of the vein 10 at junctions 18 and 20 as shown in Figure 6. As a result, the saddle 40 maintains the folded configuration of the valve region 12 of the vein 10 without the need to surgically or externally affect the vein 10 such as by bonding the vein portions together as previously described, although such procedures may be utilized in conjunction with the saddle 40 if desired.

Some embodiments of the invention may include one or more support devices. For those embodiments having two or more support devices, both devices may be positioned inside the vein, both may be positioned outside the vein, and/or one may be inside and the other outside. Other configurations for the one or more support devices are also possible. Support devices may include one or more saddle-shaped rings, one or more stents or similar structures, and/or a combination of the two. Other types of supports may include an anchor bar extending between opposite sides of the vessel,

circular or helical rings, tacks, barbs and interlocking components.

As indicated above, the present invention provides for a variety of methods for forming the folded configuration of the valve region 12, a variety of methods for preparing a selected region of the vein for folding, and a variety of methods for maintaining the valve region 12 in its folded configuration. Additionally, the present invention provides for embodiments directed to catheters and catheter systems for carrying out one or more of the various methods described.

An example of such an inventive catheter assembly, indicated generally at 100, is depicted in Figures 7-13. In Figures 7-13 the catheter 100 is shown carrying out the steps of at least one of the inventive methods for preparing the vein 10 for folding and folding a portion of the vein 10 to form the valve region and deploying a saddle 40 therein.

As is shown in Figure 7, prior to formation of the valve region the catheter 100 includes, but is not limited to, a catheter shaft 112 having at least two expandable members or balloons 114 and 116 positioned thereon. It should be recognized that it is inherent that the catheter shaft 112 defines an inflation lumen or other mechanism (not shown) for expanding the balloons 114 and 116.

Also disposed about the shaft 112 is a support device or saddle 40 in a reduced low profile configuration. The saddle 40 may be held in the reduced state by any of a variety of known retaining devices such as one or more retractable sleeves, sheathes, socks, and bioabsorbable retaining bands, which when removed from the saddle 40, the saddle is allowed to expand to its nominal or expanded state such as is shown in Figures 11-13. In embodiments where the saddle 40 is at least partially constructed of a shape memory material, the saddle may be retained in the reduced profile configuration shown in Figure 7 until the material is triggered to achieve one or more expanded states such as are shown in Figures 11-13.

In some embodiments of the invention the catheter 100 may also be equipped with one or more stents or other expandable endoprosthesis support devices. In the embodiment shown in Figure 7 the support device can be a stent 120, such as a balloon expandable stent positioned about the first balloon 114. In some embodiments support device may be self-expandable or hybrid expandable as desired and may be positioned anywhere along the catheter shaft 112 prior to delivery.

In practice the catheter 100 is advanced through the vein 10 to a selected region 118 of the vein 10 where it is desired to form a valve region. The catheter 100 is

positioned such that the balloons 114 and 116 are adjacent to the ends of the selected region 118. Once the catheter 100 is positioned in this manner, the balloons 114 and 116 are expanded such as is shown in Figure 8 to isolate the region of the vein 10 which is to be prepared for valve formation.

5 To facilitate folding the vein 10, it is desirable to collapse the vein 10 in order to facilitate engagement of the vein wall 13 to the biasing regions 44 and 46 of the saddle 40. In some embodiments of the invention the shaft 112 defines a vacuum or evacuation port 130 and an evacuation lumen 132 through which the blood present in the selected region 118 may be evacuated in order to collapse the selected region 118 of the vein 10
10 as is shown in Figure 9. In some embodiments of the invention the catheter 100 includes an injection device 134 which is advanced through the shaft 112 and passed outward through the vein wall 13 to deploy inject material 136 about the selected region 118 of the vein 10. The inject material 136 may be any material such as including but not limited to: saline, contrast medium, anesthetic solution, air, carbon dioxide, or any
15 suitable liquid, gas or combination thereof. The inject material 136 will aid in separating the vein 10 from the surrounding extra-vascular tissue and thereby aid in collapsing the isolated selected region 118 with out the need to surgically expose the vein 10.

 In some embodiments a device such as a helical wire or other device may be
20 passed around the vein 10 to limit any expansion of the vein 10 which may occur, for example, by internal device expansion such as support device, or by dilatation due to internal pressure. The helical wire or other device can be introduced from within the vein and passed through an opening created in the vein wall, or can be placed surgically.

 Once the selected region 118 of the vein 10 is collapsed, such as is shown in
25 Figure 10, the balloons 114 and 116 are collapsed and the stent 120 is deployed adjacent to the collapsed selected region 118 of the vein.

 The deployed stent 120 acts to support and define the outer portion 14 of the vein 10. Once the stent 120 is deployed the biasing regions 44 and 46 are freed to expand radially outward from the catheter shaft 112 to engage the wall 13 of the
30 selected region 118 of the vein 10, such as is shown in Figure 11. When the biasing regions 44 and 46 of the saddle 40 are initially freed to expand the opposing end(s) 45 of the saddle 40 remain in the reduced configuration engaged to the catheter shaft 112.

 As is shown in Figure 12, following the partial deployment of the saddle 40 and engagement of the vein wall 13 by the biasing regions 44 and 46, the catheter 100 is

drawn back through the deployed stent 120. Drawing the catheter 100 through the stent 120 pulls the saddle 40 as well as the portion of the vein engaged thereto through the stent 120 as well. Because the stent 120 is fixed in place within the vein 10, the vein wall 13 is forced to fold at fold point 121 about the edge of the stent 120. Thus, the portion of the vein disposed about the stent becomes the outer portion 14 of the valve region 12 and the portion of the vein 10 drawn through the stent 120 becomes the inner portion 16.

After the valve region 12 is formed in the manner described above, the ends 45 of the saddle 40 are released from the shaft 112 (shown in Figure 12) and the saddle is allowed to fully deploy within the vein 10 and the catheter may be withdrawn as shown in Figure 13. The saddle 40 retains the folded configuration of the valve region 12 in the manner previously described to provide the vein 10 with a unidirectional valve such as is shown in Figures 2 and 3.

Although the embodiments depicted in Figures 1-13 incorporate valve configurations with two valve leaflet surfaces, the present invention can also be directed to embodiments having one or more leaflets or walls 24/26 such as are depicted in Figures 14-16. So, valve configurations can include one, two, or three leaflets analogous to opposing walls 24 and 26 shown in Figures 2 and 3.

In Figures 14-15 a valve region 12 is provided with a single leaflet or wall 24/26. Figure 14 shows the vein with the leaflet 24/26 in the open configuration and Figures 15 shows the leaflet 24/26 in the closed configuration.

In the embodiment shown in Figure 16, a valve region 12 is shown having three leaflets or walls 24/26.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should

- be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all
- 5 previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.
- 10 This completes the description of the embodiments of the present invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.